K041415

AUG - 4 2004

7.0 510(k) Summary

SUBMITTER:

B. Braun Medical Inc.
901 Marcon Boulevard
Allentown, PA 18109-9341
(610) 266-0500, ext. 2597

Contact: Amy Smith, RAC
Regulatory Affairs Specialist

DEVICE NAME: EVA TPN Container

COMMON OR USUAL NAME: TPN Bag

DEVICE CLASSIFICATION: I.V. Container, 21 CFR Part 880.5025, Product Code KPE

PREDICATE DEVICE: K983294
Baxter Healthcare Corporation; All-in-One Container

DESCRIPTION:

The EVA TPN container is for use in compounding and storage of parenteral nutrition solutions prior to and during administration to a patient using an intravascular administration set. The EVA TPN container can be filled either by gravity or in conjunction with compounding equipment.

The EVA TPN container is composed of Ethylene Vinyl Acetate copolymer (EVA). The containers will be available as a single chamber bag in two configurations. One configuration will be used for filling the container by gravity. The second configuration is for use with a B. Braun Medical Inc. compounder. The containers will range in volume capacity from 250mL – 4000mL. The gravity containers can be filled using standard admixture products (spikes, tubing), and clamped after filling. The container for use with the compounder will have an adapter unique to the compounder. The tubing is composed of a DEHP-free polyvinyl chloride material. Additional medications can be added to the gravity or compounder cotnainer using the medication port. After filling, the container can then be

K041415

attached to an intravascular administration set via the set port.

INTENDED USE:

The EVA TPN container is for use in compounding and storage of parenteral nutrition solutions prior to and during administration to a patient using an intravascular administration set.

SUBSTANTIAL EQUIVALENCE:

The B. Braun Medical Inc. EVA TPN Mixing Container has similar indications for use, materials of construction, labeling and sterilization methods as the predicate device, Baxter All-in-One Mixing Container. The EVA TPN Mixing Container was tested in accordance with current international standards for containers for intravenous injections.

There are no differences between the B. Braun Medical Inc. EVA TPN Mixing Container and the predicate device that raise new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 4 2004

Ms. Amy Smith, RAC
Regulatory Affairs Specialist
B. Braun Medical, Incorporated
901 Marcon Boulevard
Allentown, Pennsylvania 18109

Re: K041415
Trade/Device Name: EVA TPN Container
Regulation Number: 880.5025
Regulation Name: I.V. Container
Regulatory Class: II
Product Code: KPE
Dated: May 27, 2004
Received: May 27, 2004

Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2.0 Indications for Use Statement

510(k) Number (if known): K041415

Device Name: EVA TPN Container

Indications For Use:

The EVA TPN container is for use in compounding and storage of parenteral nutrition solutions prior to and during administration to a patient using an intravascular administration set. The EVA TPN container can be filled either by gravity or in conjunction with automated compounding equipment.

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K041415